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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,838	06/24/2003	Birthe Lykkegaard Hansen	6423.404-US	9325

23650 7590 10/12/2006

NOVO NORDISK, INC.
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EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

7/11

Office Action Summary	Application No. 10/602,838	Applicant(s) HANSEN ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08).
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response and amendment, filed 8/7/2006, has been received.

Pursuant to amendment, claims 1 – 19, 21 – 37 are pending in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of amendment.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 27 and 28 **remain** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant argues that the claim is not directed to factor VII sequence variants per se, but to formulations containing such variants.

Art Unit: 1615

However, it is noted that since Applicant has not shown possession of the entire genus of factor VII sequence variants, it is not possible to show possession of formulations containing any factor VII sequence variant.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 9, 11, 21, 23, and 32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of amendment.

Claim 17 **remains** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' aver that the term "methionine analogues" is used in the art, and provide examples of journal articles that relate to such compounds.

However, nowhere in the art or in any evidence provided is there a limiting definition of the term "methionine analogues", nor is there any evidence showing how or why a particular compound would or would not be classified as a "methionine analogue". As such, the term is indefinite and the rejection is maintained.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1 – 3, 5 – 7, 10 – 12, 21 – 22, and 29 – 35 under 35 U.S.C. 102(b) as being anticipated by Hannam et al., US 5,649,959 is **withdrawn**. The Hannam reference does not teach the pH as now recited.

The rejection of claims 1 – 7, 9 – 16, 20 – 23, 25, 26, and 29 – 37 under 35 U.S.C. 102(b) as being anticipated by The Medicine Catalogue is **withdrawn**.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5, 6, 12, 13, 22, 30, 31 – 37 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over The Medicine Catalogue. In addition, claims 1 – 4, 7, 9 – 11, 34 – 16, 21, 23, 25, 26, and 29 must now be included in this rejection.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant argues that Figure 1 in the specification shows an unexpected result, namely, that in raising the pH between 6.0 and 7.5 there is an increase in the amount of undesirable Factor VII aggregates after three months storage at 2 – 8 degrees C.

In response, it is first noted that the showing is not commensurate with the claims. Instant claims include pH 5.5 – 7.5, whereas by Applicants' admission, the

Art Unit: 1615

showing relates only to pH 6.0 – 7.5. Secondly, it is noted that there are no comparative examples to which the results illustrated in Figure 1 can be compared. As such, there is no way to evaluate the veracity of Applicants' claim that "these results could not have been predicted", nor is there any evidence to support this argument. It is accepted that arguments cannot take the place of evidence. The teaching of The Medicine Catalogue that the compositions thereof are chemically stable for 24 hours is noted, however, this is understood to be at room temperature, so it cannot be compared to the showing in the specification. Further, chemical instability is not the same as formation of aggregates, so again, there is no evidence that the teachings of the specification show any advantage or unexpected result over that of the prior art

Claim 8 **remains** rejected under 35 U.S.C. 103(a) as being unpatentable over The Medicine Catalogue in view of WO 97/19687 for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants' argue that the '687 reference cannot overcome supposed deficiencies in The Medicine Catalogue. These alleged deficiencies have been addressed, *supra*.

Claims 17 – 19 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over The Medicine Catalogue in view of Thatcher et al., US 5,830,582.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Art Unit: 1615

Applicants' argue that the Thatcher reference cannot overcome supposed deficiencies in The Medicine Catalogue. These alleged deficiencies have been addressed, *supra*.

Claim 24 **remains** rejected under 35 U.S.C. 103(a) as being unpatentable over The Medicine Catalogue in view of Osawa et al., US 5,993,795.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' argue that the Osawa reference cannot overcome supposed deficiencies in The Medicine Catalogue. These alleged deficiencies have been addressed, *supra*.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

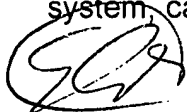
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric E. Silverman, PhD
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